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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,525	07/09/2001	Jay M. Short	DIVER1230-2	7453

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EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/902,525	SHORT ET AL.	
	Examiner	Art Unit	
	Richard G Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23,40,41,67-85 and 93-108* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23,40,41,67-85 and 93-108* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/7/2004 has been entered.

Applicants amendment of the specification, cancellation of claims 24-39, 42-66 and 86-92 and the amendment of claims 1, 3-14, 16-23, 40, 41, 67, 69-78 and 82-40, in the paper of 6/7/2004, is acknowledged. Claims 1-23, 40, 41, 67-85 and 93-108 are still at issue and are present for examination.

Applicants' arguments filed on 6/7/2004, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-14, 16-21, 22, 23, 41, 67-81, 82-85 and 93-108 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is stated in the previous office actions as it applied to previous claims 3-5, 6-14, 16-21, 22, 23, 41, 67-81, 82-85. In response to the rejection applicants have amended claims 3, 4-14, 16-23, 40, 41, 67, 69-78 and 82-40 and traverse the rejection as it applies to the newly amended and added claims.

Applicants traverse the rejection on the basis that applicants amendment has addressed any issues resulting from the office's position that the claimed genus lacks of a functional limitation. Applicants specifically note that each of the rejected claims recite "having phosphatase activity" and thus because all of the pending claims are clearly associated with a "functional limitation", applicants submit that as per the USPTO guidelines, applicants have met the requirement necessary to meet the written description or a genus of polynucleotides described by structure, physico-chemical property and a defined function. Applicants submit that this "functional" not only includes "phosphatase-encoding" but also "phosphatase-identifying". Applicants further support applicants position by referring to the attached expert declaration by Dr. Jay Short, an inventor of the instant application.

Applicants arguments and the declaration submitted by Dr. Short is fully acknowledged. In this declaration, Dr. Short declares that assays for identifying nucleic

acids that encode polypeptides such as phosphatases and that procedures for identifying polypeptides having phosphatase activity under varying conditions were conventional and routine in the art at the time of the invention. Applicants thus submit that accordingly one of ordinary skill in the art using the teaching of the specification would have been able to ascertain what phosphatase-encoding and phosphatase-identifying nucleic acids were within the scope of the claims with reasonable clarity to recognize applicants were in possession of the invention at the time of filing.

Applicants submission that that the claimed invention is fully described in the specification such that one of ordinary skill in the art would recognize that applicants were in possession of the claimed invention at the time of filing and that the description of a genus of polynucleotides in terms of the physico-chemical properties (i.e. a % sequence identity) and function (i.e. encoding a polypeptide having phosphatase activity) satisfies the description requirement. While such a description of a genus of polynucleotides in terms of the physico-chemical properties (i.e. a % sequence identity) and function (i.e. encoding a polypeptide having phosphatase activity) does satisfies the description requirement, applicants have not made such a description of the claimed genus of polynucleotides. While applicants argue that in addition to the function of phosphatase-encoding, applicants claimed genus is limited to the additional function of phosphatase-identifying. Applicants argument is acknowledged, however not found persuasive because, given the minor structural limitations of the claimed genus, applicants submission of phosphatase-identifying as a proposed function is insufficient

to adequately describe the claimed genus with respect to a stucture to function relationship.

As the supposed function and its correlated structure of the claimed genus of polynucleotides is such a minor structural feature of the overall structure of the claimed molecules of the claimed genus, applicants have not adequately described the claimed genus.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-5, 6-14, 15, 16, 17-21, 22, 23, 40, 41, 67-81, 82-85 and 93-108 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding a polypeptide having phosphatase activity, wherein said polypeptide comprises SEQ ID NO: 30, does not reasonably provide enablement for any nucleic acid or polynucleotide probe which is fully complementary to a portion of SEQ ID NO: 21. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection is stated in the previous office action as it applied to previous claims 3-5, 6-14, 15, 16-21, 22, 23, 40, 41, 67-81, 82-85. In response to the rejection applicants have amended claims 1, 3, 4-14, 16-23, 40, 41, 67, 69-78 and 82-40 and traverse the rejection as it applies to the newly amended and added claims.

Applicants maintain that the specification enabled the skilled artisan at the time of the invention to identify and make and use the genus of phosphatases-encoding and phosphatase-identifying nucleic acids of the claimed invention. Applicants assert that the state of the art at the time of invention and the level of skill of the person of ordinary skill was very high, such that it would not have taken undue experimentation to make and use the claimed invention including identification of nucleic acids encoding and identifying phosphatases.

Applicants submit that applicants amendment changing the claimed genus from those comprising at least 50% sequence identity to the exemplary nucleic acid, to 70% sequence identity, addresses any issue regarding the large variable genus encompassed by the rejected claims. This argument is not found persuasive for all of the reasons previously stated for those nucleic acids 50% identical to the exemplary sequence. As previously stated, while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan producing variants as claimed by applicants (i.e., encoding or identifying a phosphatase) requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation.

To further address this rejection, applicants submit for consideration a Rule 132 expert declaration by Dr. Jay Short. The declaration submitted by Dr. Short is fully

acknowledged. In this declaration, Dr. Short declares that procedures for modifying nucleic acids were conventional and routine in the art at the time of invention and that one of ordinary skill in the art using the teachings of the specification would have been able to select any known method of modifying nucleic acids to make a variant of SEQ ID NO: 21 or a variant of a nucleic acid having 70% sequence identity to SEQ ID NO: 21 or a variant of a nucleic acid comprising a fragment of at least 20 consecutive nucleotides of a sequence having at least 70% identity to the sequence set forth in SEQ ID NO: 21, to practice the methods of the invention without undue experimentation.

Applicants argument is not found persuasive because while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc. are well known to the skilled artisan, producing variants as claimed by applicants requires that one of ordinary skill in the art know or be provided with guidance for the selection of which of the infinite number of variants which are to be modified by the claimed method, have the claimed property (i.e. phosphatase-encoding or phosphatase-identifying). Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While applicants continue to argue that the art teaches and is enabled for numerous methods of modification of nucleic acids, the basis for the rejection is not based on the lack of enablement of the different recited nucleic acid modification methods, but rather the lack of enablement of those starting materials of the claimed methods, specifically those nucleic acids having a mere 70%

identity to the sequence set for the in SEQ ID NO: 21 or at least 20 consecutive nucleotides of said sequence.

While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Such guidance has not been provided in the instant specification. As stated previously, the specification does not support the broad scope of the claims which encompass all modifications and fragments of any polynucleotide with the defined minimal structural limitations, because the specification does not establish: (A) regions of the polynucleotide structure which may be modified without its functional activity; (B) the general tolerance of the claimed polynucleotides to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any nucleic acid residue of the polynucleotide with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Applicants declaration stating that it was considered routine by one skilled in the art at the time of the invention to screen for multiple substitutions or multiple modifications in a nucleic acid sequence for functional variations is acknowledged, however, as stated above, while methods to produce variants of a known sequence such as site-specific mutagenesis, random mutagenesis, etc, are well known to the skilled artisan, producing variants as claimed by applicants (i.e. encoding or identifying a phosphatase) requires that one of ordinary skill in the art know or be provided with

guidance for the selection of which of the infinite number of variants produced by as well as used by the claimed method, have the claimed property. Without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation.

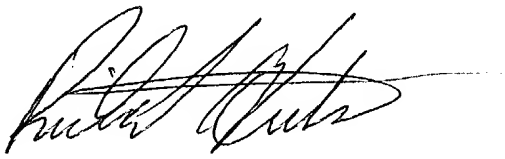
Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of modifications of any nucleic acid encoding any phosphatase, wherein said nucleic acid has a mere 70% sequence identity to SEQ ID NO: 21. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those nucleic acids having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax

phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
8/18/2004